

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF PENNSYLVANIA**

**X**

ROYAL L. KNAB, Derivatively and on :  
behalf of Nominal Defendant Discovery :  
Laboratories, Inc. :

Plaintiff,

**V.**

ROBERT J. CAPETOLA, W. THOMAS :  
AMICK, ANTONIO ESTEVE, MAX E. :  
LINK, and HERBERT H. MCDADE, JR.,

Defendants,

and

DISCOVERY LABORATORIES, INC.

### Nominal Defendant.

**X**

Civil Action No.

## VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

## JURY TRIAL DEMANDED

Plaintiff Royal L. Knab ("Plaintiff"), derivatively and on behalf of Nominal Defendant Discovery Laboratories, Inc. by and through his undersigned attorneys, and for his Complaint against Defendants herein, alleges the following based upon personal knowledge of the Plaintiff, and on information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, public announcements made by the Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Discovery Laboratories, Inc. (hereafter "Discovery" or the "Company") and information

readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a shareholder derivative action brought by Plaintiff and shareholders of Discovery against certain current or former officers and directors of Discovery seeking to remedy the Defendants' violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets, unjust enrichment and negligence that occurred from December 28, 2005 through the present, (the "Relevant Period") and that have caused substantial losses to the Company.<sup>1</sup>

2. Throughout the Relevant Period, defendants repeatedly represented that they anticipated the FDA's approval of Surfaxin in April 2006.

3. On April 25, 2006, the Company revealed that Surfaxin's "stability" (its ability to be stored for long periods without any change in its efficacy or its chemical profile) had not been achieved and that such failure would cause a "significant delay in the U.S. regulatory process." The Company admitted that although it had been testing the "product validation batches" periodically for "stability," stability had never been achieved.

---

<sup>1</sup> Because Defendants have failed to take action to remedy the breaches of fiduciary duties that occurred between December 28, 2005 and April 25, 2006, the Relevant Period continues through this day instead of ceasing on April 25, 2006, the day before the public became aware of the wrongdoings at the Company.

### **JURISDICTION AND VENUE**

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(a)(2) in that Plaintiff and Defendants are citizens of different states and the matter in controversy exceeds \$75,000.00, exclusive of interests and costs.

5. This action is not a collusive one designed to confer jurisdiction on a court of the United States which it would not otherwise have.

6. Venue is proper in this district because a substantial portion of the transactions and wrongs complained of herein, including the Individual Defendants' participation in the wrongful acts detailed herein, occurred in this district, and Discovery maintains its corporate headquarters in this District. Further, Defendants either reside in or maintain executive offices in this district, and/or have received substantial compensation in this district by engaging in numerous activities and conducting business here, which had an effect in this district.

7. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

### **THE PARTIES**

8. Plaintiff, Royal L. Knab, as set forth in the accompanying Verification, is, and was during the Relevant Period, a shareholder of Discovery. Plaintiff is a resident of the State of Florida.

9. Defendant Discovery Laboratories, Inc. is a corporation organized and existing under the laws of the state of Delaware. The Company's principal executive

offices are located in Warrington, Pennsylvania. Discovery describes itself as a biotechnology company developing its proprietary surfactant technology for respiratory diseases.

10. Defendant Robert J. Capetola ("Capetola") is a citizen of the Commonwealth of Pennsylvania. He served, at all times material to the claims set forth herein, as Discovery's President and Chief Executive Officer.

11. Defendant W. Thomas Amick ("Amick") is a citizen of the State of North Carolina. He has been a member of the Board of Directors of Discovery since September 2004.

12. Defendant Antonio Esteve ("Esteve") is a citizen of Spain. He has been a member of the Board of Directors of Discovery since May 2002.

13. Defendant Max E. Link ("Link") is a citizen of Switzerland. He has been a member of the Board of Directors of Discovery since October 1996.

14. Defendant Herbert H. McDade, Jr. ("McDade") is a citizen of the State of New York. He has been a member of the Board of Directors of Discovery since June 1996, and its Chairman since June 2000.

15. Defendants Capetola, Amick, Esteve, Link, and McDade are collectively referred to hereinafter as the "Individual Defendants."

16. Because of the Individual Defendants' positions with the Company, they had access to the adverse undisclosed information about its business, operations, operational trends, finances, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and report of actual operations compared thereto), conversations

and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and access to internal corporate documents (including the Company's operating plans, budgets and forecasts and report of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith.

17. The Individual Defendants were directly involved in the day-to-day operations of the Company at the highest levels and were privy to confidential proprietary information concerning the Company and its business, operations growth, finances, and financial condition, as alleged herein. Individual Defendants were involved in the drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware (ore recklessly disregarded) that the false and misleading statements were being issued regarding the Company and approved or ratified these statements, in violation of the federal securities laws.

18. The Individual Defendants had a duty to disseminate promptly accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, business, markets, management, and earnings, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Relevant Period violated these specific requirements and obligations.

19. The Individual Defendants had access to the adverse undisclosed information about the ongoing results of the stability testing being conducted by Discovery on Surfaxin as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Discovery and its business issued or adopted by the Company materially false and misleading.

20. Individual Defendants are liable as participants in a fraudulent scheme and course of business that disseminated materially false and misleading statements and/or concealed material adverse facts.

#### **DUTIES OF THE INDIVIDUAL DEFENDANTS**

21. By reason of their positions as officers and/or directors of the Company and because of their ability to control the business and corporate affairs of the Company, the Individual Defendants owed the Company and its shareholders the fiduciary obligations of good faith, trust, loyalty, and due care, and were and are required to use their utmost ability to control and manage the Company in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of the Company and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to the Company and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

22. The Individual Defendants, because of their positions of control and authority as directors and/or officers of the Company, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

23. To discharge their duties, the Individual Defendants were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the Individual Defendants were required to, among other things:

- a. exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;
- b. exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority; and
- c. when placed on notice of improper or imprudent conduct by the Company and/or its employees, exercise good faith in taking action to correct the misconduct and prevent its recurrence.

24. The Individual Defendants, particularly the Officers and members of the Board of Directors' Compliance and Quality Committee, were responsible for maintaining and establishing adequate internal controls for the Company and to ensure that the Company provided oversight for the development, implementation, performance and enforcement of legal and regulatory compliance programs. Among other things, the Individual Defendants were required to:

- a. Verify the adequacy of compliance and quality programs;
- b. Investigate and report non-compliance matters to the Board of Directors and applicable legal and regulatory authorities; and
- c. Establish procedures for the receipt, retention and treatment of complaints regarding compliance matters.

### **SUBSTANTIVE ALLEGATIONS**

25. Discovery is a biotechnology company that develops proprietary surfactant technology as “Surfactant” Replacement Therapies (“SRT”) for respiratory diseases. Surfaxin, the Company’s lead product, is the first precision-engineered, protein B-based agent that mimics the surface-active properties of human surfactant.

26. The company’s press releases state:

Discovery’s SRT pipeline is focused on significant respiratory conditions prevalent in the neonatal intensive care unit, critical care and other hospital settings. Discovery’s lead product, Surfaxin®, for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, has received an Approvable Letter from the FDA and is under review for approval in Europe by the EMEA.

27. On December 28, 2005, Discovery entered into an agreement to acquire the manufacturing operations of Laureate Pharma, Inc. (a wholly-owned subsidiary of Safeguard Scientifics, Inc.) in Totowa, New Jersey, for \$16 million. The Company stated that the acquisition was “intended to provide Discovery with operational control and improved economics for the potential commercial and clinical production of Discovery’s lead product, Surfaxin, and its pipeline of precision engineered SRT products.” Prior to the acquisition, Laureate Pharma had essentially been a dedicated Surfaxin operation.

28. Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery, commented:

We are preparing our organization for the anticipated approval of Surfaxin in April 2006 and its commercial launch in the second quarter. We believe our Surfactant Replacement Therapy pipeline, with Surfaxin as the cornerstone, holds the promise to revolutionize the treatment of respiratory diseases and it is strategically important to control key operations of a pharmaceutical business – from the conduct of clinical trials to the quality of manufacturing to commercializing our products. We have an established development, clinical and regulatory infrastructure and we expect to complete the build of our United States commercial sales organization by the second quarter of 2006. With this manufacturing



acquisition, we believe we will have secured the key strategic operations for Discovery to become a fully-integrated biotechnology company.

29. The press release announcing the acquisition of Laureate Pharma stated, as follows:

In October 2003, Discovery and Laureate entered into a contract manufacturing agreement, whereby Discovery's Surfaxin manufacturing know-how and dedicated equipment was transferred to this facility. Transfer of the Surfaxin manufacturing process was completed in 2004 and, since that time, the facility has been predominately dedicated to Surfaxin and the support of regulatory compliance for Discovery's manufacturing operations. **In January 2005, as part of the review of the Surfaxin New Drug Application, the FDA issued a Form 483 to Laureate, citing inspectional observation related to basic quality controls, process assurances and documentation requirements that support the commercial production necessary to comply with cGMPs. To address the inspectional observations, Discovery and Laureate have implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin.**

(Emphasis added.)

30. On January 26, 2006, the individual Defendants stated that:

Surfaxin has already received an Approvable Letter from the FDA for the prevention of RDS in premature infants and anticipates potential approval in April 2006.

31. On February 23, 2006, Individual Defendants announced financial results for the fourth quarter and year ended December 31, 2005. Robert J. Capetola, Ph.D., President and Chief Executive Officer of Discovery commented:

This past quarter, we believe we have significantly strengthened our Company, both financially and operationally in preparation for the potential FDA approval in April 2006 and U.S. commercial launch in the second quarter of 2006 of our lead product, Surfaxin. We have raised \$29.0 million in capital, secured our own manufacturing operation – a key strategic asset for Surfaxin and our pipeline, and are now in the final stage of building our specialty neonatal U.S. commercial capability. Important to the development of our surfactant replacement therapy (SRT) pipeline, we established a strategic alliance with Chrysalis Technology (a division of Philip Morris USA) where we acquired rights to a novel aerosol generating

technology being developed to enable the delivery of SRT to the deep lung. The successful application of our SRT and Chrysalis' aerosol technology holds the promise, for the first time, of producing surfactant-based therapies that may revolutionize the treatment of serious respiratory conditions such as neonatal respiratory failure, acute lung injury, chronic obstructive pulmonary disorder, asthma, cystic fibrosis and others.

32. On March 16, 2006, Discovery filed its Form 10-K for the year-ended December 31, 2005 with the SEC. In the 10-K, signed by Defendant Capetola, the Individual Defendants disclosed:

In February 2005, we received an Approvable Letter from the FDA for Surfaxin for the prevention of RDS in premature infants. As part of the review of the Surfaxin NDA, the FDA, in January 2005, issued a Form 483 to our then contract manufacturer, Laureate Pharma, Inc. citing inspectional observations related to basic quality controls, process assurances and documentation requirements that support the commercial production process necessary to comply with current good manufacturing practices (cGMPs). To address the inspectional observations, we and Laureate implemented improved quality systems and documentation controls believed to support the FDA's regulatory requirements for the approval of Surfaxin. In December 2005, we purchased the manufacturing operations of Laureate in Totowa, NJ.

Our previously submitted responses to the Approvable Letter were accepted by the FDA as a complete response as of October 5, 2005. Assuming that the corrective actions made to the Surfaxin manufacturing operation in Totowa, NJ are adequate, we anticipate that our NDA will be approved in April 2006 and that the U.S. commercial launch of Surfaxin will occur late in the second quarter of 2006.

In October 2004, the EMEA validated our Marketing Authorization Application (MAA), that we had filed previously, for clearance to market Surfaxin for the prevention and rescue treatment of RDS in premature infants in Europe. We have recently received the Day 180 List of Outstanding Issues from the Committee for Medicinal Products for Human Use (CHMP) in relation to our MAA for Surfaxin. We plan to submit a written response to all of the CHMP's outstanding issues in early April 2006 with a possible Oral Explanation before the CHMP in late June 2006. According to standard CHMP procedures, the CHMP is expected to make a recommendation on whether to grant a Marketing Authorization for Surfaxin and issue a formal Opinion in late July 2006.

\* \* \*

In January 2006, the FDA granted us Fast-Track designation for Surfaxin for the treatment and prevention of BPD in premature infants. Designation as a Fast-Track product means that the FDA has determined that the drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for such a condition, and that the FDA will facilitate and expedite the development and review of the application for the approval of the product. The FDA generally will review an NDA for a drug granted Fast-Track designation within six months instead of the typical one to three years.

33. The statements contained in ¶¶27-32 were materially false and misleading when made because Individual Defendants failed to disclose or indicate that: (1) problems regarding the manufacturing of Surfaxin existed; (2) the Company failed to disclose that manufacturing problems with Surfaxin caused instability with the drug's active ingredient; (3) the FDA's concerns regarding Surfaxin's stability would result in a significant delay in the drug's approval; and (4) as a result of the above, the Company's statements concerning Surfaxin were lacking in any reasonable basis when made. Furthermore, the Individual Defendants had knowledge of the FDA's concerns with the plant manufacturing Surfaxin as of January 2005, and yet they did nothing to correct these problems. However, they led the public to believe that the FDA's concerns had been appropriately dealt with.

34. On April 5, 2006, before the market opened, Discovery announced that it had received a second Approvable Letter from the FDA for Surfaxin. Additionally, the Company reported that additional conditions would have to be met before the drug would receive FDA approval. Specifically, Discovery stated:

Discovery Laboratories, Inc. today announced that it has received a second Approvable Letter from the U.S. Food and Drug Administration (FDA) for Discovery's lead product candidate, Surfaxin (lucinactant) for the prevention of Respiratory Distress Syndrome (RDS) in premature infants.

The Approvable Letter is an official notification from the FDA and contains conditions that must be satisfied by Discovery prior to obtaining final U.S.

marketing approval. Specifically, the FDA is requesting certain information primarily focused on the Chemistry, Manufacturing and Controls (CMC) section of the NDA. The information predominately involves the further tightening of active ingredient and drug product specifications and related controls. Consistent with previous review, the FDA does not have any clinical or statistical comments.

35. On April 18, 2006, Discovery announced updates to the inspections conducted by the Medicines and Health Products Regulatory Agency (the European agency similar to the FDA) and the FDA. Specifically, Discovery stated:

On April 12, 2006, Discovery Laboratories, Inc. (the "Company") held a conference call to provide a regulatory update on its lead product, Surfaxin<sup>®</sup> for the prevention of Respiratory Distress Syndrome (RDS) in premature infants, focusing on its U.S. New Drug Application. The update also provided information with respect to the outcomes of two recently completed regulatory authority inspections of the Company's manufacturing facility, and provided guidance regarding the Company's response to such inspections.

#### European Medicines Evaluation Agency (EMA) Inspection Update

In February 2006, the Medicines and Health Products Regulatory Agency (MHRA) conducted an on-site inspection of the Company's manufacturing facility on behalf of the EMA. Such on-site inspection is required by the EMA before the grant of a Marketing Authorization. EMA regulatory guidelines provide that manufacturing facility inspectional observations are classified into three categories: "critical," "major" and "other." The February 2006 inspectional observations report contained observations categorized only as "other."

The Company responded in writing to all of the EMA inspectional observations within 14 days of the conclusion of the inspection. The Company has not received any objections, comments or questions from the EMA to its responses to date. Since the timeline, per EMA guidance, for providing any such comments has expired, the Company considers the EMA site inspection process satisfactorily completed.

#### Food and Drug Administration (FDA) Inspection Update

The FDA concluded a three-week re-inspection of the Company's manufacturing facility on April 7, 2006. The FDA had previously conducted a pre-approval inspection of the facility in January 2005, at which time the FDA had certain observations concerning the facility's compliance with

current Good Manufacturing Practices (cGMPs). The inspection observations at that time were associated primarily with basic quality controls, process assurances and documentation requirements to support the commercial production process, to which the Company responded by implementing an extensive cGMP corrective action plan, which also included the revalidation of the media and process validation runs.

The focus of the FDA re-inspection centered on the corrective actions to the Form FDA-483 issued in January 2005, as well as related manufacturing and quality operations, systems and controls. The FDA issued an inspectional observations report (Form FDA-483) citing certain observations related predominantly to the clarification of procedures, documentation and preventative maintenance. The report did not note a requirement of re-inspection of the facility. The Company expects to submit its response to a majority of the Form FDA-483 items within the next two weeks.

One item noted on the inspection report relates to certain drug product specification issues cited in the second Approvable Letter the Company received on April 5, 2006. The Company plans on responding to this inspectional item in its complete response to the second Approvable Letter. The Company believes that its satisfactory response to all of the observations contained in the re-inspection report will preclude the need for re-inspection of the manufacturing facility by the FDA prior to approval. However, in accordance with FDA practice, the agency may re-inspect the facility at any time.

36. On April 19, 2006, Discovery announced that it had entered into a new Committed Equity Financing Facility (CEFF) with Kingsbridge Capital Ltd. ("Kingsbridge"), in which Kingsbridge had committed to provide up to \$50 million of capital to support Discovery's future growth. John G. Cooper, Executive Vice President and Chief Financial Officer of Discovery, commented:

This new CEFF, coupled with our existing cash, should provide us with financial resources adequate to progress Surfaxin® through the final stages of the U.S. and European regulatory review and approval processes for our initial indication, Respiratory Distress Syndrome in premature infants. In addition, it will allow us to support our manufacturing and commercialization initiatives and our key SRT pipeline programs, Surfaxin for Bronchopulmonary Dysplasia and Aerosurf™.

37. Then, on April 24, 2006, after the market closed, Discovery issued a press release entitled "Discovery Labs Report Surfaxin Manufacturing Issue." The Company stated:

Discovery Labs Reports Surfaxin Manufacturing Issue  
Discovery Laboratories, Inc., today is announcing that analysis of ongoing stability data from Surfaxin process validation batches indicates that certain stability parameters have not been achieved and, therefore, additional process validation batches will likely have to be produced. These process validation batches were previously manufactured as a requirement for Discovery's U.S. NDA regulatory approval and have been going periodic stability testing. Discovery anticipates a potentially significant delay in the U.S. regulatory process for Surfaxin for the prevention of Respiratory Distress Syndrome (RDS) in premature infants. At this time, it is not known whether this issue will have any impact on the Surfaxin European regulatory approval process.

\* \* \*

Discovery is analyzing all aspects of its business with an immediate intention to conserve cash. The establishment of a commercial infrastructure is no longer in Discovery's near-term plans. The Company's focus will be on remediating these manufacturing issues, developing its Surfactant Replacement Therapy pipeline and potentially entering into strategic partnerships.

38. Subsequently, on May 4, 2006, Discovery issued a press release entitled "Discovery Labs Announces Corporate Reorganization and Personnel Reduction." The press release stated:

Discovery Laboratories, Inc. (Nasdaq: DSCO), today announced that it has reduced the number of employees and reorganized corporate management in order to lower its cost structure and appropriately align Discovery's operations with business priorities. **Discovery is taking these actions based upon its current expectations of the financial impact of a delay in the regulatory approval and commercial launch of Surfaxin® for Respiratory Distress Syndrome (RDS) in premature infants.** The Company is reducing its workforce by 55 employees which represents approximately 34% of its workforce. The reduction is across all functions of the Company but with a primary emphasis on the commercial infrastructure which is no longer in Discovery's near-term plans.



\* \* \*

Discovery recently reduced its personnel from 160 to 105 employees. Affected employees are eligible for certain severance payments and continuation of benefits. The Company expects to realize annual expense savings of approximately \$8.0 million from the reduction in work force and related operating expenses. Additionally, sales and marketing program expenses totaled approximately \$5.0 million over the past two fiscal quarters (Q4 '05 and Q1 '06), and these expenses will no longer be incurred. **The Company expects to take a one-time restructuring charge of approximately \$4.5 to \$5.0 million in the second quarter ending June 30, 2006 related to the staff reductions and the wind down of certain commercial programs.**

In connection with the reorganization, which includes the discontinuance of the commercial infrastructure, three senior executives will be leaving Discovery: Christopher J. Schaber, Ph.D., Executive Vice President and Chief Operating Officer; Deni M. Zodda, Ph.D., Senior Vice President of Business Development; and Mark G. Osterman, Senior Vice President of Sales and Marketing.

(Emphasis added.)

39. Finally, on May 9, 2006, the Company announced that it was concluding its Phase 2 clinical trial of Surfaxin for the treatment of Bronchopulmonary Dysplasia early. Specifically, the Company stated:

On May 9, 2006, with enrollment totaling approximately 130 patients, the Company determined to conclude early its Phase 2 clinical trial of Surfaxin for the prevention and treatment of Bronchopulmonary Dysplasia (BPD) in premature infants. **This action is related to the potential financial impact of the Surfaxin manufacturing issues that are anticipated to significantly delay the regulatory approval of Surfaxin for RDS and may adversely affect the availability of Surfaxin drug product for this trial.** This double-blind, controlled Phase 2 clinical trial was intended to enroll up to 210 very low birth weight premature infants born at risk for developing BPD. The study's objective is to determine the safety and tolerability of administering Surfaxin for the prevention and treatment of BPD. The Company plans to perform a comprehensive analysis of the clinical data from this trial, report top-line results, and submit these data for publication.

(Emphasis added.)

40. Defendants were aware that the FDA conducted a pre-approval inspection of the manufacturing facility in January 2005 which resulted in the issuance of a Form FDA-483. The company responded by implementing an extensive cGMP corrective action plan. Subsequently, the FDA spent three weeks inspecting the facility in March and April 2006, concluding on April 7, 2006 after receipt of the second Approval Letter. Defendants were clearly aware of the FDA inspections, the FDA's continued concern with the manufacturing processes and facilities and the resulting delay in approval which would occur. The failure to adequately address these concerns has led to the delay in regulatory approval for Surfaxin – the Company's key product – and the early conclusion of Phase 2 clinical trials.

41. The Individual Defendants were motivated to get Surfaxin on the market, no matter what, because, according to the Company's Proxy Statement filed with the SEC on April 21, 2006, Defendant Capetola owns 15,000 shares of restricted stock that will not fully vest until Surfaxin for RDS becomes widely commercially available.

#### **DEMAND WOULD BE FUTILE**

42. Plaintiff brings this action derivatively in the right and for the benefit of Discovery to redress injuries suffered and to be suffered by Discovery as a result of the breaches of fiduciary duty by the Individual Defendants. This is not a collusive action to confer jurisdiction on this Court which it would not otherwise have.

43. Plaintiff will adequately and fairly represent the interests of Discovery and its shareholders in enforcing and prosecuting its rights.



44. Plaintiff is an owner of Discovery common stock and was an owner of Discovery common stock at all times relevant to the Individual Defendants' wrongful course of conduct alleged herein.

45. Derivative Plaintiff has not made a demand on the Board of Directors to bring these causes of action because such a demand would be futile. At the time these derivative actions were commenced, the board of directors consisted of six members: W. Thomas Amick, Robert J. Capetola, Antonio Esteve, Max E. Link, Herbert H. McDade, Jr., and Marvin E. Rosenthale. As detailed below, each of the directors are subject to substantial liability on these derivative claims and are therefore in no position to render a disinterested judgment on whether the Company should bring them, and/or lack sufficient independence with which to render a disinterested decision on whether to pursue the Derivative Claims against the Individual Defendants.

46. All of these directors face a substantial likelihood of liability in this action because of their failure, as directors, to assure that a reliable system of financial controls was in place and functioning effectively. The dramatic breakdowns and gaps in those controls were so widespread and systematic that the entire board faces substantial exposure to liability, under the *Caremark* doctrine, for their total abrogation of their duty of oversight. These directors either knew or should have known that violations of law were occurring and took no steps in a good faith effort to prevent or remedy that situation, proximately causing hundreds of millions of dollars of losses for the Company.

**Additional Likelihood of Substantial Liability of the Compliance and Quality Committee Defendants.**

47. Defendants Amick and Link also had enhanced responsibilities as members of the Company's Compliance and Quality Committee. That Committee was charged with direct responsibility for the development, implementation, performance and enforcement of legal and regulatory compliance programs.

48. Given the FDA inspections, the FDA's continued concern with the manufacturing processes and facilities and the resulting delay in approval which would occur, the Compliance and Quality Committee members either knew of the problems with the manufacturing processes and facilities or turned a blind eye to them. Such conduct is not protected by the business judgment rule and exposes these Individual Defendants to a substantial threat of liability in this action.

49. In addition, should Defendants Amick and Link decide to bring claims against themselves, that would likely trigger an "insured vs. insured" exclusion which is typical for D&O insurance policies, which would make D&O insurance coverage unavailable to them.

**The Directors Lack Independence**

50. Director Marvin E. Rosenthale has been a member of the Board of Directors of Discovery since September 1998.

51. Director Defendant Capetola, as the Company's current CEO, lacks the sufficient independence with which to render a disinterested decision on whether to pursue the Derivative Claims against the Individual Defendants.

52. Director Defendant Capetola held a variety of positions at Johnson & Johnson Pharmaceutical Research Institute from 1977 to 1992, including Senior

Worldwide Director of Experimental Therapeutics. Director Defendant McDade served as Vice President, Drug Discovery worldwide at the R.W. Johnson Pharmaceutical Research Institute from 1990 to 1993. McDade also performed drug discovery research for Ortho Pharmaceutical from 1977 to 1990. Ortho Pharmaceutical is part of the Johnson & Johnson family of companies. Director Defendant Amick, during this time, also held various positions with Johnson & Johnson, including Ortho Biotech. Because of their inter-related business, professional and personal relationships, Defendant Directors Capetola, Amick and McDade have developed debilitating conflicts of interest that prevent them from having the sufficient independence with which to render a disinterested decision on whether to pursue the Derivative Claims against the Individual Defendants.

53. Director Defendant Capetola served as Chairman and CEO of Acute Therapeutics, Inc., which was a majority-owned subsidiary of Discovery, from 1996 to 1998. During this same period of time, Director Defendant Link and Director Rosenthale served as directors of Acute Therapeutics. Because of their inter-related business, professional and personal relationships, Defendant Directors Capetola, and Link and Director Rosenthale have developed debilitating conflicts of interest that prevent them from having the sufficient independence with which to render a disinterested decision on whether to pursue the Derivative Claims against the Individual Defendants.

54. Defendant Director Esteve is President of one of the Company's collaborative partners, Laboratorios del Dr. Esteve, S.A. In October 2005, Discovery

sold 650,000 shares of Common Stock to Laboratorios del Dr. Esteve, S.A., giving this entity the beneficial ownership of 5.31% of the outstanding shares of Discovery.

55. In addition, demand would be a futile and useless for the additional following reasons:

- a. The Directors of Discovery, as more fully detailed herein, participated in, approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from Discovery's stockholders or recklessly and/or negligently disregarded the wrongs complained of herein, and are therefore not disinterested parties. Each of the Directors exhibited a sustained and systemic failure to fulfill their fiduciary duties, which could not have been an exercise of good faith business judgment and amounted to gross negligence and extreme recklessness;
- b. In order to bring this suit, a majority of the Directors of Discovery would be forced to sue themselves and persons with whom they have extensive business and personal entanglements, which they will not do, thereby excusing demand;
- c. The acts complained of constitute violations of the fiduciary duties owed by Discovery's officers and directors and these acts are incapable of ratification; and
- d. Discovery has been and will continue to be exposed to significant losses due to the wrongdoing complained of herein, yet the Individual Defendants and current Board have not filed any lawsuits against themselves or others who were responsible for that wrongful conduct to attempt to recover for Discovery any part of the damages Discovery suffered and will suffer thereby;

56. Plaintiff has not made any demand on the shareholders of Discovery to institute this action since demand would be a futile and useless act for the following reasons:

- a. Discovery is a publicly held company with approximately 61.14 million shares outstanding, and thousands of shareholders;
- b. Making demand on such a number of shareholders would be impossible for Plaintiff, who has no way of finding out the names, addresses or phone numbers of all the shareholders; and

- c. Making demand on all shareholders would force Plaintiff to incur huge expenses, assuming all shareholders could be individually identified.

57. Discovery has expended and will continue to expend significant sums of money as a result of the illegal and improper actions described above. Such expenditures will include, but are not limited to:

- a. Costs incurred to carry out internal investigations, including legal fees paid to outside counsel and experts;
- b. Costs incurred to implementing the corrective action plan; and
- c. Costs/damages incurred because of the delay in approval of Surfaxin.

### **FIRST CAUSE OF ACTION**

#### **Against Individual Defendants for Breach of Fiduciary Duty**

58. Plaintiff incorporates by reference and reallege each and every allegation set forth above as if set forth fully herein.

59. The Individual Defendants owed and owe Discovery fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Discovery the highest obligation of good faith, fair dealing, loyalty and due care.

60. The Individual Defendants, and each of them, violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, oversight, good faith and supervision.

61. The Individual Defendants had actual or constructive knowledge that they had caused the Company to improperly misrepresent the business prospects of the Company and failed to correct the Company's public announcements. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

62. As a direct and proximate result of the Individual Defendants' failure to perform their fiduciary obligations, Discovery has sustained significant damages. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

63. Plaintiff, on behalf of Discovery, has no adequate remedy at law.

## **SECOND CAUSE OF ACTION**

### **Against The Individual Defendants for Abuse of Control**

64. Plaintiff incorporates by reference and reallege each and every allegation set forth above as if set forth fully herein.

65. The Individual Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Discovery, for which they are legally responsible.

66. As a direct and proximate result of the Individual Defendants' abuse of control, Discovery has sustained significant damages.

67. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company.

68. Plaintiff, on behalf of Discovery, has no adequate remedy at law.

## **THIRD CAUSE OF ACTION**

### **Against The Individual Defendants for Gross Mismanagement**

69. Plaintiff incorporates by reference and reallege each and every allegation set forth above as if set forth fully herein.

70. By their actions alleged herein, the Individual Defendants, either directly or through aiding and abetting, abandoned and abdicated their responsibilities and fiduciary duties with regard to prudently managing the assets and business of Discovery in a manner consistent with the operations of a publicly held corporation.

71. As a direct and proximate result of the Individual Defendants' gross mismanagement and breaches of duty alleged herein, Discovery has sustained significant damages in excess of millions of dollars.

72. As a result of the misconduct and breaches of duty alleged herein, the Individual Defendants are liable to the Company.

73. Plaintiff, on behalf of Discovery, has no adequate remedy at law.

#### **FOURTH CAUSE OF ACTION**

##### **Against The Individual Defendants for Waste of Corporate Assets**

74. Plaintiff incorporates by reference and reallege each and every allegation set forth above as if set forth fully herein.

75. As a result of the Individual Defendants' improper conduct and by failing to properly consider the interests of the Company and its public shareholders by failing to conduct proper supervision, Individual Defendants have caused Discovery to waste valuable corporate assets by paying bonuses to certain of its executive officers and incur potentially millions of dollars of legal liability and/or legal costs to defend the Individual Defendants' unlawful actions.

76. As a result of the waste of corporate assets, Individual Defendants are liable to the Company.

77. Plaintiff, on behalf of Discovery, has no adequate remedy at law.

## **FIFTH CAUSE OF ACTION**

### **Against The Director Defendants for Unjust Enrichment**

78. Plaintiff incorporates by reference and reallege each and every allegation set forth above as if set forth fully herein.

79. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of Discovery.

80. Plaintiff, as shareholder and representative of Discovery, seeks restitution from the Individual Defendants, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by the Individual Defendants, from their wrongful conduct and fiduciary breaches.

## **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Against the Individual Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the Individual Defendants' breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment;

B. Extraordinary equitable and/or injunctive relief as permitted by law, equity and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on or otherwise restricting the proceeds of the Individual



Defendants' trading activities or their other assets so as to ensure that Plaintiff has an effective remedy;

C. Awarding to Discovery restitution from the Individual Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by these Defendants;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: May 15, 2006

Respectfully submitted,



---

Marc S. Henzel  
LAW OFFICES OF MARC HENZEL  
273 Montgomery Ave., Suite 202  
Bala Cynwyd, PA 19004  
Telephone: (610) 660-8000  
Fax: (610) 660-8080  
[Mhenzel182@mhenzellaw.com](mailto:Mhenzel182@mhenzellaw.com)

---

William B. Federman  
FEDERMAN & SHERWOOD  
120 N. Robinson, Suite 2720  
Oklahoma City, OK 73102  
Phone: (405) 235-1560  
Fax: (405) 239-2112  
[wfederman@aol.com](mailto:wfederman@aol.com)